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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,912	10/04/2004	Takahiro Ito	0020-5301PUS1	4489

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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
03/04/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/509,912	ITO ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 Dec 2008 and 11 Dec 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05 Dec 2008 has been entered.

This Office Action is responsive to Applicant's Amendment and Remarks, filed 05 Dec 2008, in which claims 1-19 are canceled and new claims 20-34 are added; the ITO Declaration, filed 05 Dec 2008; the SHINDO Declaration, filed 05 Dec 2008; and Applicant's Remarks, filed 11 Dec 2008.

The instant application is the 371 national stage entry of PCT/JP03/04745, filed 15 Apr 2003; and claims benefit of foreign priority document JP 2002- 112864, filed 16 Apr 2002; currently an English language translation of this foreign priority document has not been made of record.

Claims 20-34 are pending.

Rejections Withdrawn

Applicant's Amendment, filed 05 Dec 2008, with respect to claims 1-6, 8, 10-13, 16 and 17 rejected under 35 U.S.C. 102(b) as being anticipated by Harada et al. (Journal of Controlled Release, 2000, 69, p399-412, of record) has been fully considered and is persuasive, as claims 1-6, 8, 10-13, 16 and 17 are canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 05 Dec 2008, with respect to claims 1, 9, and 14-19 rejected under 35 U.S.C. 103(a) as being unpatentable over Harada et al (Journal of Controlled Release, 2000, 69, p399-412, of record) in view of Wall et al. (US patent 5,340,817, issued 23 Aug 1994, of record) has been fully considered and is persuasive, as claims 1, 9 and 14-19 are canceled.

This rejection has been **withdrawn**.

Specification

The disclosure is objected to because of the following informalities: at page 5, line 13 it appears as if the term "mercapto group" is misspelled "mercapt group".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended claims 20-23 and 30-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 20-23 recite "wherein R^1 is a substituted or unsubstituted lower alkyl group" (emphasis added). Claims 30-34 depend from claims 20-23 and incorporate all limitations therein.

The specification discloses chemical groups, such as wherein R^1 is C_2H_5 in claim 24, substituents such as hydroxyl group, a mercapto group and an amino group at page 5, lines 10-15, and specific protecting groups such as alkyl or acyl at page 5, lines 14-15 which meet the written description and enablement provisions of 35 USC 112, first paragraph for these particular substituted groups. However, claims 20-23 and 30-34 are directed to encompass substituted lower alkyl groups and the specification discloses protected substituents at page 5, lines 13-15, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these substituents and protecting groups meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and because chemical substituents and protecting groups are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim. The specification provides only non-limiting examples of substituents and protecting groups at page 5, lines 10-15.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must

convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed substituents and protecting groups, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the structurally defined chemical compounds, but not the full breadth of the claims, meet the written description provision of 35 USC § 112, first

paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See Vas-Cath at page 1115.)

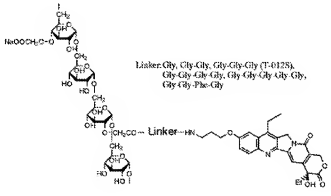
The court of *In re Curtis* held that "a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when... the evidence indicates ordinary artisans could not predict the operability ... of any other species." (see *In re Curtis* 354 F.3d 1347, 69 USPQ2d 1274, Fed. Cir. 2004). The court of *Noelle v. Lederman* also pointed out that generic claim to anti-CD40CR Mabs lacked written description support because there was no description of anti-human or other species Mabs, and no description of human CD40CR antigen. The court further pointed out that attempt to "define an unknown by its binding affinity to another unknown" failed. See 355 F.3d 1343, 69 USPQ2d 1508, Fed. Cir. 2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended claims 20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Harada et al. (Journal of Controlled Release, 2000, 69, p399-412, of record).

Harada et al. discloses the compound T-0128, "a novel [camptothecin] analog (T-2513: 7-ethyl-10- aminopropyloxy-[camptothecin]) bound to carboxymethyl (CM) dextran through a Gly- Gly-Gly linker" (page 399, abstract lines 1-3). The compound T-0128 has the formula 

(page 401, figure 1). Harada et al. discloses a liquid preparation comprising the camptothecin analog T-0128 and an acetate buffer, reduced glutathione, EDTA, and Triton X-100, which are stabilizers or fillers, adjusted to pH 7 using acetate or phosphate buffers, optionally with $CaCl_2$, an alkaline earth metal chloride, added (page 402, right column, section 2.4. *In vitro evaluation of drug release*), meeting limitations of instant claims 20 and 22. According to the SHINDO Declaration provided by Applicant, filed 05 Dec 2008, Harada et al. discloses a solution comprising 1.0 w/v% of T-0128 in saline absent a buffer, and a solution comprising 0.01 w/v% of T-0128 in the presence of a buffer. However, these disclosed examples do not constitute a teaching away from the broader disclosure of Harada et al., and Harada et al. would have reasonably suggested to one having ordinary skill the art to instantly envision a solution comprising 1.0 w/v% of T-0128 in the presence of a buffer based on the broader disclosure of Harada et al. and the disclosed exampled, meeting limitations of instant claims 20 and 22.

Claims 20 and 22 recite a product-by-process. It is apparent from what is disclosed that the product disclosed in the prior art is the same as the instantly claimed product-by-process. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113.

Response to Applicant's Remarks:

Applicant's Remarks, filed 05 Dec 2008 and 11 Dec 2008, have been fully considered and found not to be persuasive.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52,

190 USPQ 461, 463 (CCPA 1976) (emphasis in original) ... For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See MPEP 2111.03. It is noted that the specification indicates the liquid preparation of the present invention can contain conventional ingredients used for injection as well as the camptothecin compound or salt thereof, buffer and water, such as fillers, solubilizing agents, stabilizers, antioxidants, tonicity agents, and preservatives (page 8, lines 10-25). In view of the specification and claims as filed, there is no clear indication of what the basic and novel characteristics of the invention actually are, therefore "consisting essentially of" will be construed as equivalent to "comprising" with regards to fillers, solubilizing agents, stabilizers, antioxidants, tonicity agents, and preservatives.

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied,* 493 U.S. 975 (1989). ... Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi,* 440 F.2d 442, 169 USPQ 423 (CCPA 1971). See MPEP 2123. The SHINDO

Declaration provides evidence that the prior art Harada et al. discloses a solution comprising 1.0 w/v% of T-0128 in saline absent a buffer, and a solution comprising 0.01 w/v% of T-0128 in the presence of a buffer. However, these disclosed examples do not constitute a teaching away from the broader disclosure of Harada et al., and Harada et al. would have reasonably suggested to one having ordinary skill the art to instantly envision a solution comprising 1.0 w/v% of T-0128 in the presence of a buffer based on the broader disclosure of Harada et al. and the disclosed exampled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended claims 21 and 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harada et al (Journal of Controlled Release, 2000, 69, p399-412, of record) in view of Wall et al. (US Patent 5,340,817, issued 23 Aug 1994, of record), herein the '817 Patent, and in view of Wall et al. (US Patent 6,288,072, issued 11 Sep 2001, cited in PTO-892), herein the '072 Patent.

Harada et al. discloses as above. The acetate or phosphate buffers are disclosed at a concentration of 40 mM (page 402, right column, section 2.4. *In vitro evaluation of drug release*), which gives an ionic strength of less than 0.2.

Harada et al. does not specifically disclose the composition comprising one or more stabilizers selected from alkali metal carbonate or alkali metal hydrogen carbonate (instant claims 21 and 23). Harada et al. does not specifically disclose the composition wherein the buffer is one comprising citric acid and sodium dihydrogenphosphate (instant claim 24). Harada et al. does not specifically disclose the lyophilized drug composition prepared by lyophilizing the liquid preparation (instant claim 29 and 31-34).

The '817 Patent teaches a camptothecin analog that is a water-soluble derivative of camptothecin bound to an amino acid or peptide (column 8, lines 19-22) "incorporated into a solution or suspension. The solutions or suspensions may also include the following components: a sterile diluent such as water for injection, saline solution... buffers such as acetates, citrates or phosphates and agents for the adjustment of tonicity such as sodium chloride or dextrose." (column 13, lines 14-27). The '817 Patent also teaches oral liquid compositions of a camptothecin analog, such as capsules, elixirs, suspensions, syrups, which generally include an inert diluent or an

edible carrier and incorporated with excipients (column 13, lines 29-36). The '817 Patent teaches the lyophilization of liquid preparations to provide the camptothecin derivatives (column 18, lines 30-31 and 52-53). The '817 Patent teaches the camptothecin compound is compatible in solution with sodium bicarbonate, an alkali metal hydrogen carbonate (column 18, lines 15-20 and 40).

The '072 Patent teaches amino acid esters of camptothecin compounds (abstract) in pharmaceutically acceptable compositions (column 8, lines 15-20). The '072 Patent teaches well-known excipients for said camptothecin compositions are the inert diluent calcium carbonate and sodium carbonate (column 8, line 50).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the liquid preparation of the camptothecin analog disclosed by Harada et al. with the pharmaceutical excipients in the pharmaceutical compositions of an amino acid- or peptide-bound camptothecin analog and the lyophilization of a liquid composition of a water-soluble amino acid-bound camptothecin analog taught by the '817 Patent and the pharmaceutical excipients in the pharmaceutical compositions of an amino acid-bound camptothecin analog taught by the '072 Patent. One of ordinary skill in the art at the time of the invention would be motivated to combine the references because the '817 Patent teaches the need for additional water-soluble camptothecin analogs (column 2 lines 2-5). It would have been obvious to substitute well-known excipients of pharmaceutical compositions containing a camptothecin compound taught the '817 Patent and the '072 Patent because these excipients are known in the art for the same purpose. One of ordinary skill in the art at the time of the invention would

have a reasonable expectation of success in combining these references due to the similarity between the the camptothecin analog disclosed by Harada et al. and the amino acid-bound camptothecin analog taught by the '817 Patent and the '072 Patent.

Claims 21 and 23-34 recite a product-by-process. It is apparent from what is disclosed that the product made obvious by the teachings of the prior art is the same as the instantly claimed product-by-process. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113.

Response to Applicant's Remarks:

Applicant's Remarks, filed 05 Dec 2008 and 11 Dec 2008, have been fully considered and found not to be persuasive.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) ... For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See MPEP 2111.03. It is noted that the specification indicates the liquid preparation of the present invention can contain conventional ingredients used for injection as well as the camptothecin compound or salt thereof, buffer and water, such as fillers, solubilizing agents, stabilizers, antioxidants, tonicity agents, and preservatives (page 8, lines 10-25). In view of the specification and claims as filed, there is no clear indication of what the basic and novel characteristics of the invention actually are, therefore "consisting essentially of" will be construed as equivalent to "comprising" with regards to fillers, solubilizing agents, stabilizers, antioxidants, tonicity agents, and preservatives.

Applicant provides evidence in the ITO Declaration to compare the stabilization of the preparation containing sorbitol and the preparation not containing sorbitol. Notably, the specification discloses the sugar alcohol mannitol, a sorbitol stereoisomer,

at page 8, line 15 as a well-known filler. As "consisting essentially of" will be construed as equivalent to "comprising" as detailed above, this is evidence is not persuasive as both preparations are interpreted as being encompassed within the instant invention.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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